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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,641	09/29/2004	Christian Drohmann	53383	4300

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EXAMINER	
POPOVICS, ROBERT J	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,641	DROHMANN ET AL.	
	Examiner	Art Unit	
	/Robert James Popovics/	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed through **December 4, 2008**.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ***10/10/08 & 12/4/08***
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse is noted:

> In compliance with the requirements of 37 C.F.R. §1.143, applicants provisionally elect group 1, "Polyolefins" of the "A" species and group 5 "Crosslinked Polyvinyllactams" of the "B" species. Claims 11 – 27 are readable on the elected species. This provisional election is submitted without traverse.

The election of species requirement is made **FINAL**.

Official Notice

Official Notice of the following is taken:

1) ***Polystyrene*** is a well known conventional filtration aid.

2) ***PVPP*** is a well known conventional filtration aid and/or stabilization agent

3) ***Compounding*** is a well known conventional technique for mixing polymers and/or/with other materials. Conventionally known twin screw extruders are often used to compound or mix polymers and/or/with other materials.

4) ***Popcorn polymerization*** is a well known conventional polymerization method in which the growing polymer chains are crosslinked to one another. The resultant popcorn polymers are generally insoluble and scarcely swellable.

5) Those skilled in the art are aware of Official Notice statements 1-4.

Claim Rejections - 35 USC § 103

Claims **11-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of **Klein (US 4,344,846)** and **Butterworth (US 3,958,023)** and **BASF's "60th Anniversary of Povidone"** (recently made of record by Applicants).

Butterworth discloses the use of **PVPP** admixed with conventional filter aids to treat liquids. (see column 2 and claims 1 and 4 of Butterworth). **Butterworth** does not expressly disclose polystyrene. **Klein** discloses the use of polystyrene as a filtration aid.

BASF ExAct page 4 – No.2, July 1999

More densely crosslinked PVP is prepared by copoly-merization of N-vinylpyrrolidone with bifunctional mo-nomers. Because of the combination of high water uptake and insolubility, swelling is observed with crosslinked PVP when exposed to water while soluble PVP simply dissolves.
The popcorn polymerization – bulk polymerization of N-vinylpyrrolidone either in presence of alkali metal hydroxide above 100°C or in presence of small amounts of bifunctional monomers at 100°C – leads to highly crosslinked PVP particles with a specific sur-face area of a few square meters per gram. This pop-corn PVP, Crospovidone, finds important use as tablet disintegrant, as an agent for clarifying beverages and as active ingredient for stomach and gastrointestinal diseases. In contrast to soluble PVP, complexes of crosslinked PVP with high complexation constants en-able the extraction of the complexed molecule. The usefulness of crosslinked PVP for gastrointestinal dis-eases is based on the following properties:

Complex formation of crosslinked PVP with tannin is of interest both in pharmacology and in beverage technology [illegible]. Tannin is a biopolymer with poly-phenol structures. The complexation constant of tannin with Kollidon CL is >1000 L mol^{-1} (in 0.1 N hydrochloric acid).

Particle size distribution plays a more crucial role for the application properties of crosslinked PVP as com-pared to soluble grades. The properties of Kollidon grades as a disintegrant for tablets vary with particle size (**Table 3**) [illegible]. In tablets obtained from Kollidon by compression the disintegration time decreases with the particle size of the PVP used for the formulation. Like soluble PVP, Kollidon CL-M is capable of stabilizing suspensions, such as antibiotics, antacids, vitamin preparations and topical formulations.
Lately it has been demonstrated, that pH-controlled drug release is possible from PVP/Polyacrylic acid interpenetrating networks [illegible]. Radiation-cured hydrogels of PVP, polyethylene glycol, and agar have many desirable properties for using as wound dressings [illegible].

3 Polymer/Drug Melt Extrusion

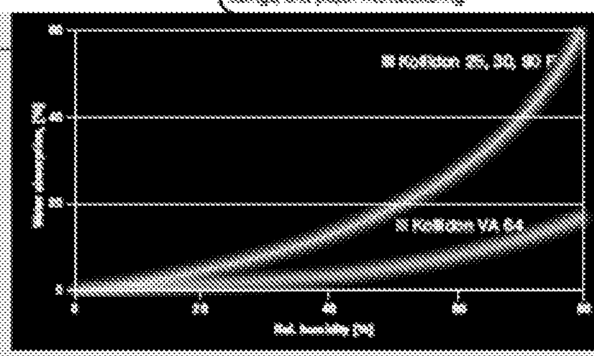
As a result of close collaboration over the past ten years, Knoll AG and its parent company BASF have developed a patent-protected novel pharmaceutical manufacturing technology: drug is incorporated by melt extrusion in a matrix consisting of a pharma-ceutical polymer. Due to its thermoplasticity and balanced aqueous solubility properties, Kollidon grades have been found to provide a comprehensive and universal base for various types of drugs. After melt extrusion, the active drug can be present in the extrudate in one or two forms: as a crystal suspended in the hardened Kollidon matrix, or as a molecule dissolved in the polymer during the melting phase and remaining dissolved in the finished product – a "solid solution". Melt extrusion technology paves the way for benefits in therapy (**Figure 5**):

Properties of insoluble PVP grades (**Table 3**)

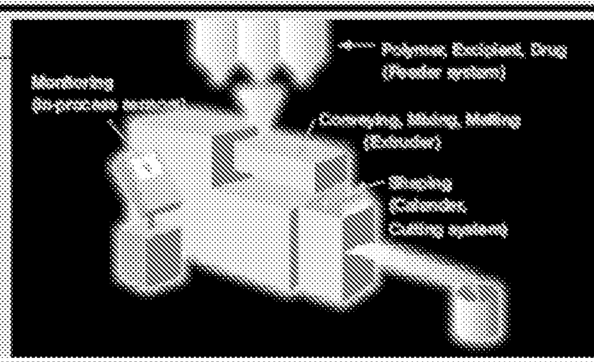
Property	[illegible]	Kollidon CL	Kollidon CL-M	[illegible]
Particle size [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Bulk density	[illegible]	[illegible]	[illegible]	[illegible]
Specific surface area [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

4 Miscellaneous Applications

...ither pharmaceutical, biomedical and biochemical a...pplications cover protein isolation and protein stabi-lization [illegible]. Besides pharmaceutical u...ses, technical grades of PVP are used throughout the i...ndustry. Applications cover cosmetics and toiletries, b...everage filtration, photographic products, dyeing a...pplications and inks, detergents, dispersions, sus-p...ensions and emulsions, adhesives, paints and c...oatings, and paper manufacturing.



Hygroscopicity of Kollidon VA 64 and Kollidon 25, 30 or 90 F for comparison, after 7 days at 25 °C (**Figure 4**)



Polymer/Drug Melt Extrusion: Product is either tablet, granules, pellet, sheet... (**Figure 5**)

BASF's "60th Anniversary of Povidone" published in July of 1999, teaches the melt extrusion of PVPP with other compunds. Beverage treatment applications are clearly mentioned, as indicated in the annotated copy of page 4 above. The Official notice statement concerning **compounding** is noted and relied upon. In view of **BASF's "60th Anniversary of Povidone,"** it would have been obvious to one skilled in the art to melt extrude (i.e., compound) polystyrene with PVPP in order to practice the invention of **Butterworth**. The huge ranges of percentages claimed cover almost the entirety of possibilities. Absent a showing of criticality or unexpected result specifically associated the extremely broad ranges claimed, the selection of any combination of percentages would have been readily apparent to the skilled artisan, given the teachings of Butterworth and/or Klein.

Response to Arguments

Applicants' arguments with respect to claims **11-27** have been considered but are moot in view of the new ground(s) of rejection. Applicants have argued:

> The Examiner's position does not seem to be internally consistent. In the Official Notice statements, the Examiner has alleged that compounding is a type of mixing. Yet, in the rejection, the Examiner has equated "mixing" and "compounding." Equating a teaching "to admix" with a teaching "to compound" is not consistent with an allegation that compounding is a type of mixing.
>
> The Examiner has pointed to no apparent reason for a skilled artisan "to compound" polystyrene with PVPP. A teaching "to admix" does not obviate a teaching "to compound," merely because "compounding" is alleged to be a type of "mixing."

For the record, the examiner has alleged nothing. The examiner formulated the rejection in light of the terms as defined in Applicants specification. As defined in Applicants' specification:

> Compounding is generally mixing a polymer with at least one additive (*Der Doppelschneckenextruder : Grundlagen- und Anwendungsgebiete [The double-screw extruder : Principles and areas of application], edited by: VDI-Gesellschaft Kunststofftechnik.-Düsseldorf : VDI-Verlag, 1995, Chapter 7* and

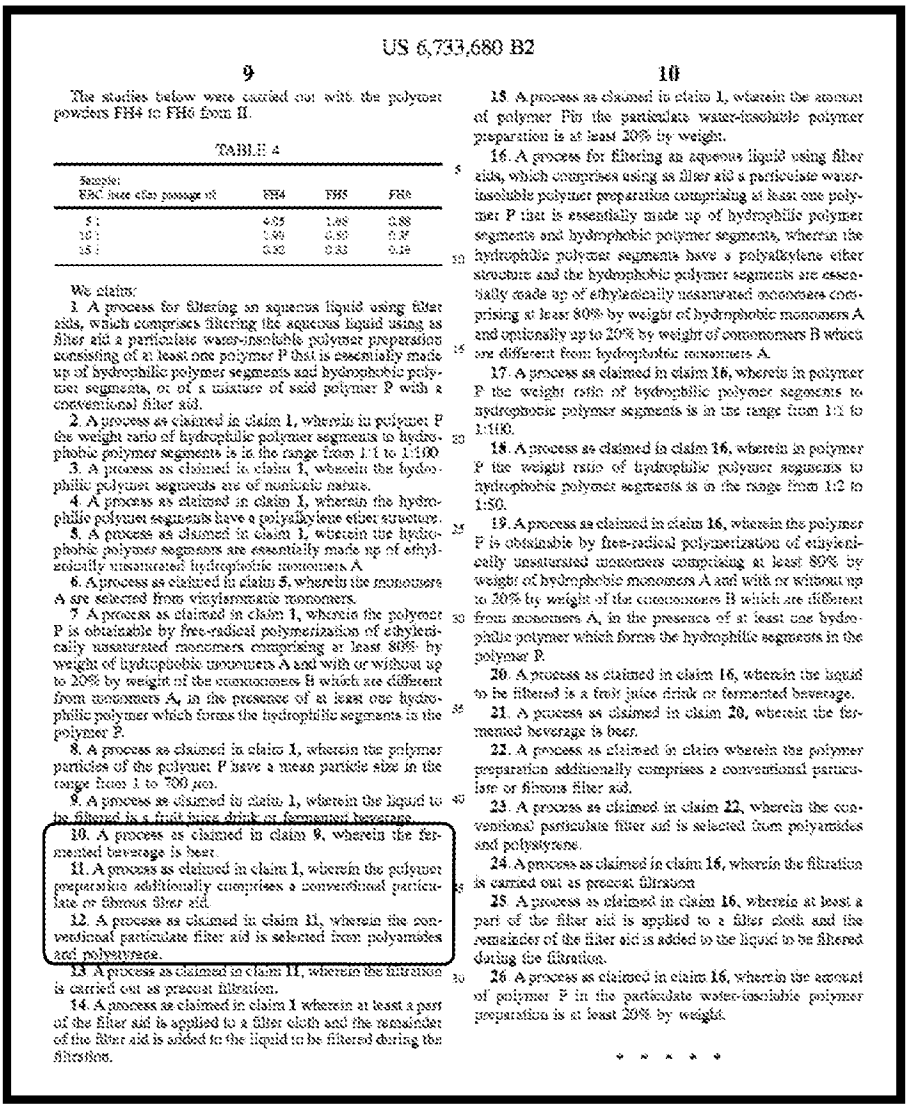
> The filter aids are comminuted after the mixing process by techniques of pelletizing, shredding and/or grinding, preferably by a sequence of pelletizing and grinding. At the temperature profile of a cold grinding process, water may remain in the final product.

As is clear from these excerpts, Applicants (and not the examiner) have equated the terms ***"mixing"*** and ***"compounding,"*** and have used the terms interchangeably. If Applicants intended something more to be read into the term ***"compounding,"*** the specification should have made that clear. As Applicants are undoubtedly aware, an

applicant may be his own lexicographer. And he must live with that definition. For these reasons, the ***after-the-fact*** attempt to redefine the term ***"compounding,"*** cannot be found to be persuasive.

Response to OFFICIAL NOTICE Traversals

1) ***Polystyrene*** is a well known conventional filtration aid. **See claim 12 of United States Patent 6,733,680.**



US 6,733,680 B2

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The studies below were carried out with the polymer powders FH4 to FH6 from II.

TABLE 4

Sample: EBC haze after passage of	FH4	FH5	FH6
5 l	0.85	1.06	0.88
10 l	1.09	0.80	0.87
15 l	0.92	0.83	0.89

We claim:

1. A process for filtering an aqueous liquid using filter aids, which comprises filtering the aqueous liquid using as filter aid a particulate water-insoluble polymer preparation consisting of at least one polymer P that is essentially made up of hydrophilic polymer segments and hydrophobic polymer segments, or of a mixture of said polymer P with a conventional filter aid.

2. A process as claimed in claim 1, wherein in polymer P the weight ratio of hydrophilic polymer segments to hydrophobic polymer segments is in the range from 1:1 to 1:100.

3. A process as claimed in claim 1, wherein the hydrophilic polymer segments are of nonionic nature.

4. A process as claimed in claim 1, wherein the hydrophilic polymer segments have a polyalkylene ether structure.

5. A process as claimed in claim 1, wherein the hydrophobic polymer segments are essentially made up of ethylenically unsaturated hydrophobic monomers A.

6. A process as claimed in claim 5, wherein the monomers A are selected from vinylaromatic monomers.

7. A process as claimed in claim 1, wherein the polymer P is obtainable by free-radical polymerization of ethylenically unsaturated monomers comprising at least 80% by weight of hydrophobic monomers A and with or without up to 20% by weight of the comonomers B which are different from monomers A, in the presence of at least one hydrophilic polymer which forms the hydrophilic segments in the polymer P.

8. A process as claimed in claim 1, wherein the polymer particles of the polymer P have a mean particle size in the range from 1 to 700 μm.

9. A process as claimed in claim 1, wherein the liquid to be filtered is a fruit juice drink or fermented beverage.

10. A process as claimed in claim 9, wherein the fermented beverage is beer.

11. A process as claimed in claim 1, wherein the polymer preparation additionally comprises a conventional particulate or fibrous filter aid.

12. A process as claimed in claim 11, wherein the conventional particulate filter aid is selected from polyamides and polystyrene.

13. A process as claimed in claim 11, wherein the filtration is carried out as precoat filtration.

14. A process as claimed in claim 1 wherein at least a part of the filter aid is applied to a filter cloth and the remainder of the filter aid is added to the liquid to be filtered during the filtration.

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15. A process as claimed in claim 1, wherein the amount of polymer P in the particulate water-insoluble polymer preparation is at least 20% by weight.

16. A process for filtering an aqueous liquid using filter aids, which comprises using as filter aid a particulate water-insoluble polymer preparation comprising at least one polymer P that is essentially made up of hydrophilic polymer segments and hydrophobic polymer segments, wherein the hydrophilic polymer segments have a polyalkylene ether structure and the hydrophobic polymer segments are essentially made up of ethylenically unsaturated monomers comprising at least 80% by weight of hydrophobic monomers A and optionally up to 20% by weight of comonomers B which are different from hydrophobic monomers A.

17. A process as claimed in claim 16, wherein in polymer P the weight ratio of hydrophilic polymer segments to hydrophobic polymer segments is in the range from 1:1 to 1:100.

18. A process as claimed in claim 16, wherein in polymer P the weight ratio of hydrophilic polymer segments to hydrophobic polymer segments is in the range from 1:2 to 1:50.

19. A process as claimed in claim 16, wherein the polymer P is obtainable by free-radical polymerization of ethylenically unsaturated monomers comprising at least 80% by weight of hydrophobic monomers A and with or without up to 20% by weight of the comonomers B which are different from monomers A, in the presence of at least one hydrophilic polymer which forms the hydrophilic segments in the polymer P.

20. A process as claimed in claim 16, wherein the liquid to be filtered is a fruit juice drink or fermented beverage.

21. A process as claimed in claim 20, wherein the fermented beverage is beer.

22. A process as claimed in claim wherein the polymer preparation additionally comprises a conventional particulate or fibrous filter aid.

23. A process as claimed in claim 22, wherein the conventional particulate filter aid is selected from polyamides and polystyrene.

24. A process as claimed in claim 16, wherein the filtration is carried out as precoat filtration.

25. A process as claimed in claim 16, wherein at least a part of the filter aid is applied to a filter cloth and the remainder of the filter aid is added to the liquid to be filtered during the filtration.

26. A process as claimed in claim 16, wherein the amount of polymer P in the particulate water-insoluble polymer preparation is at least 20% by weight.

* * * * *

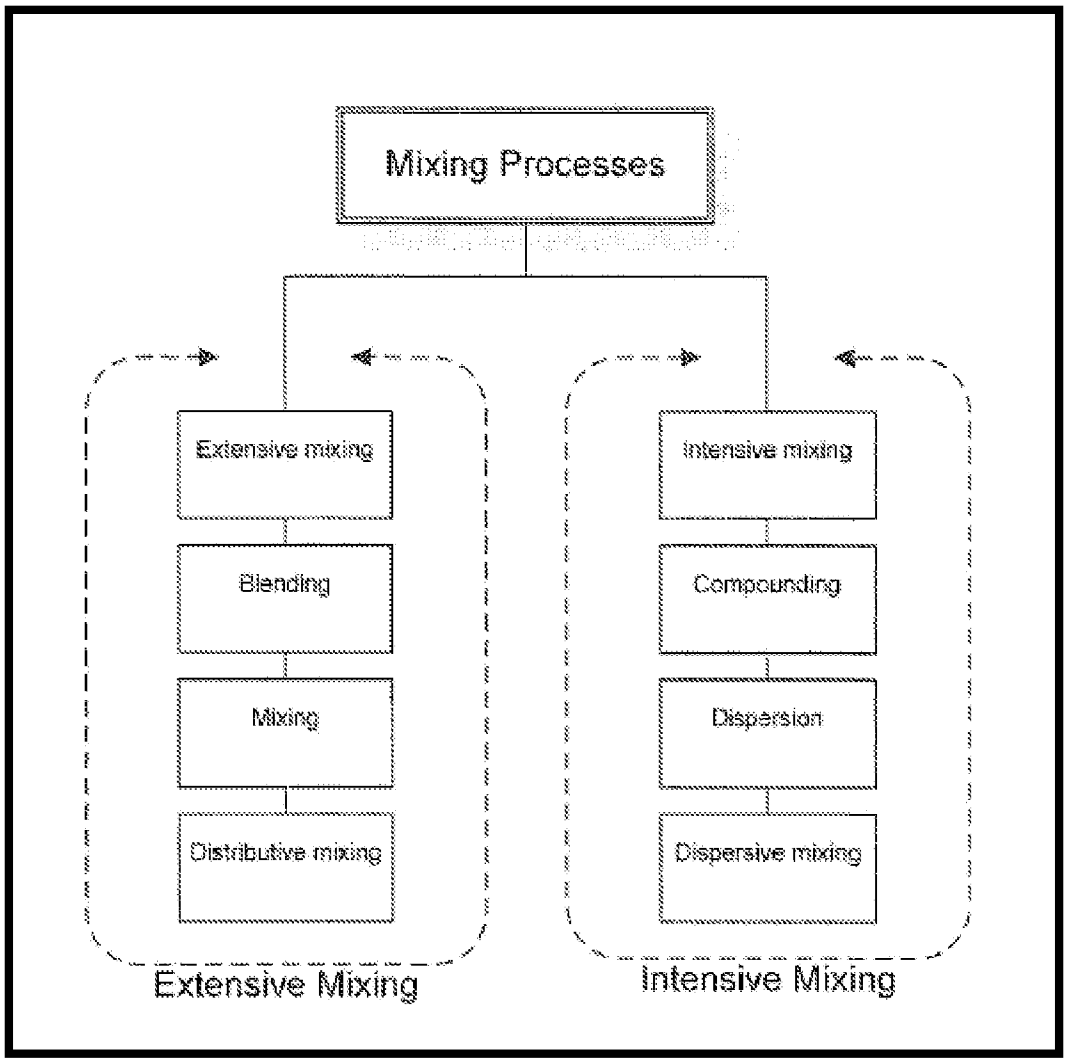
2) ***PVPP*** is a well known conventional filtration aid and/or stabilization agent. **See the discussions of PVPP in US 6,117,459, the use of PVPP in Klein (US 4,344,846).** It is noted that the arguments traversing this Official Notice statement raise issues pertaining to the instant claims, as it is noted that they do not specify ***"highly"*** crosslinked PVPP, but merely, ***"crosslinked."*** Also see BASF **Fine Chemicals Brochure – Excipients & Actives for Pharma** – recently made of record by Applicants.

3) ***Compounding*** is a well known conventional technique for mixing polymers and/or/with other materials. Conventionally known twin screw extruders are often used to compound or mix polymers and/or/with other materials. Again, from Applicants' Specification:

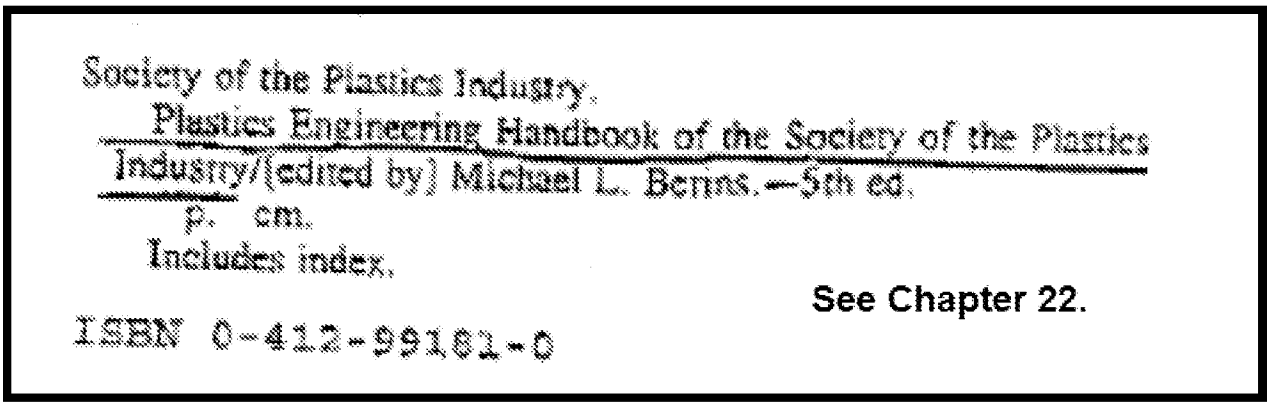
> The reaction can also take place via customary processes for thermoplastics, in particular mixing, dispersing, filling, reinforcing, blending, degassing, and reactive compounding by rolling, kneading, casting, sintering, pressing, compounding, calandering, extrusion or combination of these methods. However, preferably, the polymer powders are compounded in an extruder.

Here, it is interesting to note that Applicants break out the terms **"reactive compounding," "compounding"** and **"extrusion"** as separate **"customary processes"** without explanation.

It is unclear where **"reactive compounding"** and **"extrusion"** fall out in Applicants' cited diagram:



It should be noted here, that the examiner has equated the terms ***"customary"*** and ***"conventional."*** Also, see:


Society of the Plastics Industry.
Plastics Engineering Handbook of the Society of the Plastics Industry/(edited by) Michael L. Berins.—5th ed.
p. cm.
Includes index.
ISBN 0-412-99181-0

See Chapter 22.

4) ***Popcorn polymerization*** is a well known conventional polymerization method in which the growing polymer chains are crosslinked to one another. The resultant popcorn polymers are generally insoluble and scarcely swellable. See **BASF Fine Chemicals Brochure – Excipients & Actives for Pharma** – recently made of record by Applicants. It is noted that this Official Notice statement is not needed or relied on at the present time, as no claims are drawn to popcorn polymerization.

Response to Amendment

The Declarations filed under 37 CFR 1.132 filed **December 11, 2006** have been again considered. First and foremost, the Declaration specifies polymer powder "D" to be a ***"compound,"*** whereas the instant independent claims 11-27 do not specify a "***compound.***" Thus, powder "D" is not commensurate in scope with the claims. For this reason alone, the Declaration cannot be found persuasive.

Additionally, the following assertion is made:

> This experiment show difference in the behaviour of the four materiasl in water. Only with material that gives sedimentation and chemically and physically homogeneus distribution in the water phase it is possible to obtain a pre-coat filter that is chemically and physically homogeneus.

Yet, Applicants provide no documentary evidence establishing the assertions made (i.e., that only, "material that gives sedimentation ... is possible to pre-coat a filter"). Here, it is noted that Applicants have claimed a "filter-aid or stabilizer," yet present evidence in their Declaration that only attempts to disqualify the powders with respect to the "filter-aid," while nothing is said about the stabilization aspect which is claimed in the alternative. ***It is noted that claim 12 of US Patent 6,733,680 specifies polystyrene to be a conventional filter aid, while the Declaration submitted by Applicants indicates polystyrene to be unsuitable for use as a filter aid?*** Additionally, it is noted that the densities of the materials used are not provided. It is submitted that one reviewing such experimental results, especially in view of the results, would want to know the densities of the materials used. Beyond that, it is noted that polymer powders of greatly different mean particle diameters were employed. It is unclear why materials of the same mean particle diameter were not used? The use of differing mean particle diameters injects yet another variable into the analysis equation. For these reasons, he Declarations filed under 37 CFR 1.132 filed **December 11, 2006** are not seen to establish unexpected results.

The submission of Applicants' Interview Record of **May 6, 2008** is acknowledged.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on **October 10, 2008** prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to /Robert James Popovics/ at telephone number (571) 272-1164.

/Robert James Popovics/
Primary Examiner
Art Unit 1797